

### REMARKS

Reconsideration and re-examination are respectfully requested in view of the below remarks. No amendments have been made to the claims, although they have been included in this response for the convenience of the Examiner.

The Examiner is thanked for the thorough explanation of his reasoning in the office action.

#### Rejections under 35 U.S.C. §101 and §112

Claims 1-2, 4-5, 7, 9-10, 22-23, 25-29 and 31-33 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Claims 9-10 and 23 were rejected under 35 U.S.C. §112 as indefinite. Applicant has endeavored to overcome these rejections through amendment of the claims, in particular to add the language of 'transforming' of images which is an underlying theme of the present invention, as well as to address the indefiniteness issues. Accordingly, in view of the above amendments it is requested that the rejection be withdrawn.

#### Rejections under 35 U.S.C. §102

Claims 1-2 and 4-5 stand rejected under 35 U.S.C. §102(e) as being unpatentable over U.S. Patent 5,657,362, hereinafter Giger.

One item at issue is whether Giger describes "processing a digital or digitized x-ray medical image of an object to remove *"distinguishing effects of an operating parameter ... used to form said x-ray medical image"* or *"distinguishing effects of ... physical characteristics of an x-ray device used to form said x-ray medical image"* and *"the effects of fat content in the object being imaged..."*

With regard to whether Giger teaches “processing a digital or digitized x-ray medical image of an object *to remove “distinguishing effects of an operating parameter” or “distinguishing effects of ... a physical characteristic of an x-ray device used to form said x-ray medical image and the effects of fat content in the object being imaged...*”, the Examiner appears to rely heavily on the teachings of Giger in column 5, lines 57-65. Applicant has reproduced this section below, with certain terms emphasized by the Applicant.

FIGS. 6A-6D illustrates the subtraction of the fat pixels. FIG. 6A corresponds to the original image shown in FIG. 3A after subtraction of the **gray level corresponding to fat**. FIG. 6B is a binary image of FIG. 6A. FIG. 6C corresponds to the original image shown in FIG. 3B after subtraction of the **gray level corresponding to fat**. FIG. 6D is a binary image of FIG. 6C. Note that the small isolated pixels can be removed by processing, e.g., with a morphological open operation. **This subtraction process can be performed in terms of gray level or in terms of relative x-ray exposure (by use of the characteristic curve of the imaging system).** After subtraction of the fatty level, the image can now be processed by the multi-gray-level thresholding and the feature analysis stages of the bilateral subtraction method. Multi-gray-level thresholding and feature analysis techniques are described in application Ser. No. 08/158,389 to Giger et al, the disclosure of which is herein incorporated by reference.

The Examiner maintains that the above text, and in particular the statement ‘the subtraction process can be performed ...in terms of relative x-ray exposure...’ teaches the limitation of processing an image ‘to remove distinguishing effects of’ and ‘operating parameter or physical characteristic *of an x-ray device...*’

However, Giger does not remove distinguishing effects of an x-ray device. Rather, Giger teaches removing pixels that are characterized as ‘fat’ pixels. The fat pixels may be characterized based on a gray level, or based on the relative x-ray exposure value of the pixel; but in all instances, what Giger describes is the processing of the image to remove the “fat pixels”. Giger *does not* describe processing the image to remove effects of an operating

parameter, or processing the image to remove effects of a physical characteristic of the x-ray device. These effects are not *removed* in Giger; rather a threshold is applied, and some of the effects (i.e., pixels) are kept, while others (i.e., fat) are removed. Applicant would respectfully submit that what Giger *is* removing is an effect within the *image*, (i.e., a fat pixel) rather than a distinguishing effect of the device *used to obtain* the image (i.e., an operating parameter or a physical characteristic of the device).

However, what cannot be ignored is that the Applicant's claim, in addition to reciting that the distinguishing effects of the operating parameter or physical characteristics of the x-ray device are removed *also* recites that fat pixels are removed. Thus Applicant's claim clearly recites the processing of the image to remove *at least two* effects (image effects [fat] and distinguishing effects associated with how the image is obtained). Giger, in contrast, discloses *only* removing fat pixels, even though Giger mentions two different ways of determining which of the pixels are fat.

As best Applicant can determine, it appears that the Examiner is relying on the fact that Giger mentions that x-ray exposure characteristics can be used to identify fat pixels, and thus x-ray exposure characteristics may be subtracted to remove fat pixels as teaching that something *other* than fat pixels is removed. Such a reading contradicts the actual teaching of Giger, who, presenting gray levels *OR* exposure values as alternatives for fat identification obviously did not appreciate an advantage to removing *distinguishing effects of an operating parameter or a physical characteristic an x-ray device in addition to fat pixels*.

Accordingly, for at least the reason that Giger fails to disclose both processing the image to remove fat pixels and processing the image to remove distinguishing effects of operating

parameters or physical characteristics of the x-ray device used to obtain the image, it is respectfully requested that the rejection under 35 U.S.C. §102 be withdrawn.

With regard to the Examiner's contention that the predetermined values are analogous to the gray level or exposure values of the original image in Giger, it is noted that such an interpretation gives an interpretation gives no patentable weight to the language of the claims, namely that the predetermined values are 'of an operating parameter or a physical characteristic of the x-ray device...' and that the resulting standard form "...image characterizing the x-ray medical image of the object that would have been obtained by the x-ray device using said predetermined values therefore..." While the gray level or exposure values of the original image may *result* from an operating parameter or physical characteristic of the x-ray device, but *they are not the operating parameter or characteristic themselves*. The Examiner appears to give no patentable weight to the limitations of the claims which tie the predetermined value directly to the operating parameter or the physical characteristic of the x-ray device. Accordingly, for this additional reason it is requested that the rejection of claim 1 be withdrawn.

Claims 2, 4 and 5 serve to further limit claim 1 and are therefore allowable for at least the same reasons as claim 1. However, it is noted that the Examiner has also failed to give patentable weight to several of the limitations of these claims. For example, claim 5 recites "...The method of claim 1 wherein the processing removes distinguishing effects of the following physical characteristics of the x-ray device resulting from at least one of anode material; source to image distance; anti-scatter grid geometry; film characteristics; and screen-film system..." The Examiner states, at page 9 of the office action that Giger teaches these limitations at step fig. 8, item 803. However such an interpretation of Giger is grossly overreaching; Giger merely describes, with regard to steps 802 and 803 that 'Background trend

correction is performed using a 2-dimensional surface fit in which pixels below the threshold (fatty) are not included in determining the fit (setp 802). The 2-D fit is then subtracted from the dense regions. Applicant fails to see *how* this teaches or describing processing removing distinguishing effects resulting from at least one of anode material, source to image distance, anti-scatter grid geometry, etc. For this additional reason it is submitted that the rejection of claim 5 is improper and requested that it be withdrawn.

In addition, it is respectfully submitted that Giger does not show or describe transforming the digital image into a "standard form image" as recited in the claims. The Examiner states, at page 4 of the office action in essence that Giger does disclose a standard-form version if 'standard-form' is interpreted as ... the original version. Such reasoning fails to take into account the well known and accepted meaning of the word 'standard' which is described in Meriam Webster online dictionary as **"3: something established by authority, custom, or general consent as a model or example"** Rather, using the Examiner reasoning, arguably the image would change for each breast that is x-rayed, and the 'standard' would not be 'standard' but would rather be variable, and dynamic. Accordingly, for the additional reason that Giger fails to describe transforming an image into a standard-form image, claim 1 is patentably distinct over the references and it is requested that the rejection be withdrawn.

#### Rejections under 35 U.S.C. §103

Claim 7 (and 25?) was rejected under 35 U.S.C. §103(a) as unpatentable over the combination of Giger in view of Johns. Claims 9-10 and 26-27 were rejected under 35 U.S.C. §103(a) as unpatentable over Giger in view of Santurtun. Claims 22-23 and 33 were rejected

under 35 U.S.C. §103(a) as unpatentable over Giger in view of Saito. Claims 28-29 were rejected under 35 U.S.C. §103 as unpatentable over Johns in view of Giger and Saito.

Claim 7 recites : The method of claim 1 wherein an x-ray image of a reference material is formed at the same time as the mammogram and under the same conditions, said *reference material having known x-ray attenuation characteristics representative of different percentages of fat content in the breast*, said method further comprising the step of identifying fat content in the mammogram by comparing exposure values in the mammogram with exposure values on the x-ray image of the reference material..." Claim 25 recites a similar limitation.

It is first noted that the John reference, which describes attenuation of different materials, fails to overcome the inadequacies described above with regard to the parent claim; thus John also fails to show or describe processing an image to remove distinguishing effects of operating parameters or physical characteristics of the x-ray device. Accordingly, claim 7 is allowable for at least the reason that it serves to limit an allowable parent claim.

. In addition, the John reference fails to state that the x-ray image of the reference material is *formed at the same time as the mammogram and under the same conditions...* For at least this reason, it is respectfully submitted that claims 7 and 25 are patentably distinct over the combination of references and it is requested that the rejection be withdrawn.

#### Claims 9-10 and 26-27

Claims 9-10 and 26-27 were rejected under 35 U.S.C. §103(a) as unpatentable over Giger in view of Santurtun. Claims 31-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Giger in view of Saito and Santurtun.

#### Santurtun:

Santurtun describes, in the Abstract, an “X-ray generator system is provided with a high-voltage feedback loop for controlling the output of an inverter to thereby maintain a desired output voltage level. The voltage-feedback loop is provided with a phase-advance network to selectively vary the gain of the system in such a way as to provide for high gain during the initial stage so as to obtain a short rise time, while subsequently reducing the gain so as to clamp the kV overshoot at the end of the rise time. A phase-lag network is also included to effectively eliminate noise that is introduced by the phase-advance network...” The Examiner appears to rely on Santurun’s mention of an x-ray energy having a range of 25-28 kVp as teaching the limitations of the claimed invention.

However, even if Santurtun mentions a typically used kVp and mA, there is no mention or suggestion in Santurtun of a *standard-form image*, which has been generated by processing using predetermined values. Thus, Santurtun fails to overcome the inadequacies described above in Giger. For at least these reasons it is requested that the rejection of claims 9-10 and 26-27 and 31-32 be withdrawn.

Claims 22-23 and 33

Claims 22-23 and 33 were rejected under 35 U.S.C. §103(a) as unpatentable over Giger and further in view of Saito.

Saito:

Saito describes, in the Abstract “... A display screen of an image display section is divided into an image display area for displaying an image and an operation panel display area, an image (base image) imaged by an X-ray CT apparatus, for example, is displayed on the upper part (base area) of the image display area, an image (match image) imaged by a MRI apparatus is

displayed in the middle part (match area), and an operation panel, which is composed of an operation panel display area 2 of the image display section and respective operation keys for aligning the images, is displayed thereon. When the operation panel is operated and fit points are provided to the images or a region of interest (ROI) is set on the base image, a CPU aligns and composes the respective images based on the fit points or ROI, and displays the fusion image on the lower part (fusion area) of the image display area. As a result, both the images can be compared with each other visually...”

Thus Saito describes a system where images from different sources are aligned on a display device for viewing.

Claim 22 recites the steps of : “processing a plurality of digital or digitized mammograms formed by different x-ray mammography systems to remove effects of each mammography system and fat content in the breast being imaged, thereby forming first processed images; *converting each first processed image into a standard-form x-ray mammogram having a first standard x-ray voltage parameter and a first standard exposure parameter ...* “ As described above, while Giger may process a digitized mammogram to remove effects using a subtraction technique described at column 5 ‘in terms of gray levels or x-ray exposures’, the Examiner has maintained that the *converting* of this image is analogous to the step of normalization in Giger. There is no mention or suggestion in Giger that the normalization is performed based on *first original x-ray voltage parameter and first original exposure parameter* as claimed. Rather, Giger mentions only that normalization ‘match(es) the average gray level of the original image). In addition, Giger neither suggests or describes processing the image to remove *both fat and* distinguishing effects of the mammography system, as recited in claim 22.



Saito fails to overcome any deficiencies in Giger and the combination of remaining references. The Examiner states that 'gray value levels from the standard form image ... are interpreted to be both a 'first standard x-ray voltage parameter' and 'first standard exposure parameter'; however, as mentioned above this cannot be so, as the gray level values are merely a *result* of many input factors, including breast density, etc. Accordingly, for at least the reason that the references fail to teach the limitations of the claims, it is requested that the rejection of the claims be withdrawn.

#### Conclusion

Accordingly, in view of the above remarks it is believed that this application is now in condition for allowance, and a notice to this effect is therefore solicited. It is believed that a one month extension of time is due with the filing of this response. The Examiner is hereby authorized to charge our deposit account **502855** the \$130.00 fee due for the filing of this response.

If the Examiner believes a telephone interview would expedite prosecution of this application, the Examiner is invited to call applicant's attorney at the number given below.

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Customer No. 38732

Respectfully submitted,  
/Lindsay G. McGuinness/  
Lindsay G. McGuinness  
Attorney for Applicant  
Reg. No. 38,549  
Hologic Inc.  
250 Campus Drive  
Marlboro MA 01752  
(781) 999 7339